ADDITIONAL SOURCES OF ADVERSE REACTION AND INJURY REPORTS

I. Purpose:

This guide identifies sources of adverse reactions and injury reports resulting from the use of veterinary products.

II. Additional Sources of Adverse Reaction and Injury Reports:

A. Consumer Injury Complaints:

1. Letters to the Food and Drug Administration (FDA). In the case of products sold directly to the public, injuries and adverse reactions are sometimes reported directly to FDA in the form of letters. The exact office within FDA responsible for replying to the consumer complaints and injuries will vary according to the manner in which the inquiry reaches FDA. Normally the Division of Compliance, HFV-230 will be responsible for the response.

2. Reports to the District Offices. Letters, telephone complaints or personal visits may be made to the District offices. These are noted, acknowledged and in some cases investigated to some degree and forwarded to Headquarters from the District Offices. The response is normally made through the Division of Compliance.

3. Congress. Some consumers address their complaints to their senator and/or representative. These reports may be forwarded to FDA. The Office of Legislative Affairs (OLA, HFW-1) coordinates the handling of Congressional correspondence and may refer the inquiry to the Center for Veterinary Medicine for a proposed response. (See CVM Guide 1240.2302 - Routing of Congressional Correspondence.)

a. Unless specifically authorized by the referring congressman, replies are not made to the consumer, but to the congressman forwarding the complaint, who then answers his constituent.

b. The incoming material may be only a summary or excerpt of the letter of complaint. If the information supplied is not sufficient for evaluation, a tactful reply to this effect must be sent to the congressman.

c. The congressman should be notified of any follow-up action such as a field interview with the consumer, preferably in advance, unless the injury is of such a nature that immediate action is necessary.

4. Other Government Agencies. Inquiries and complaints are frequently sent to the President, Public Health Service, Federal Trade Commission, Department of Agriculture, etc. All these complaints are referred for "necessary action" and may be treated in the same manner as complaints sent directly to the Food and Drug Administration unless other handling is specifically warranted.

B. Complaints and Inquiries from Veterinarians. A complaint or inquiry from a veterinarian is traditionally answered by a Veterinary Medical Officer (see CVM Guide 1240.2310 - Correspondence to Practicing Veterinarians, Veterinary Medical Associations and other Scientific Disciplines). Letters of reply are prepared in the Division of Epidemiology and Surveillance or in the Division of Animal Feeds. Inquiries made by a veterinarian dealing with his/her marketing of a drug are treated as other manufacturer inquiries and handled by the Division of Compliance. The source of veterinarian complaints is the same as those from consumers with additions:

1. Direct - Letter or Form FD 1932a - Veterinary Adverse Reaction, Lack of Effectiveness, or Product Defect Report (See CVM Guide 1240.3514.)

C. Scientific Literature. In addition, Veterinary Medical Officers and other scientists may read, or have brought to their attention, articles concerning drugs under our jurisdiction.

D. Reports of Foreign Governments:

1. Change of status of drug (most often removal from the market) is reported to the Food and Drug Administration through formal diplomatic channels by the ministry of health of the nation involved. These require special handling because of diplomatic protocol. The Office of International Affairs , FDA, HFG-1 will be helpful in these instances.

2. Inquiries as to status of a drug in the United States may be prompted by the occurrence of unusual or frequent injuries.

E. Reports from Industry. Many consumers, producers and veterinarians will contact the manufacturer of a drug or other product rather than the Food and Drug Administration.

1. These reports may be submitted voluntarily by the manufacturer. The manufacturer is required to forward reports of adverse reactions involving approved NADAs.

2. Other reports or even required reports may be uncovered in the course of routine or special inspections.

F. Establishment Inspection Reports. Inspections may be made to investigate a specific complaint or as a routine matter. In either instance, complaint files are usually reviewed.